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| 09/973,945 | 10/11/2001 | Susheng Gan | 50229-287 | 5823 |
| 20277 | 7590 | 09/01/2004 | EXAMINER | |
| MCDERMOTT WILL & EMERY LLP | | | LY, CHEYNE D | |
| 600 13TH STREET, N.W. | | | ART UNIT | |
| WASHINGTON, DC 20005-3096 | | | PAPER NUMBER | |

1631

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

3M

Office Action Summary

Application No.

09/973,945

Applicant(s)

GAN ET AL.

Examiner

Cheyne D Ly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2004 and June 16, 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 12-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicants' arguments filed March 11, 2004 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. Claims 1-11, SEQ ID NO. 9, are examined on the merits.

OBJECTIONS

3. Claim 2 is objected to due to the inclusion of subject matter, which has been non-elected due to a restriction requirement and therefore, the non-elected subject matter has been withdrawn from consideration.

RESPONSE TO ARGUMENT

4. Applicant argues that the included non-elected subject matter in claim 2 are merely the complements or variants of SEQ ID NO:9. Applicant's argument has been fully considered and found to be unpersuasive because sequences that are complements or variants of SEQ ID NO:9 could reasonably be construed as being patentably distinct from the sequence of SEQ ID NO:9. It is noted that only those sequences which are patentably indistinct from the selected sequences are examined together.

CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. This rejection is necessitated by Applicant's amendments.

8. Specific to claims 1 and 11, line 5, the phrase "its complement" causes said claims to be vague and indefinite because it is unclear whether the term "its" refers to SEQ ID NO:9 or "the variant". The term "complement" further causes said claims to be vague and indefinite because it is unclear what criteria are being used to consider a complement. Is a sequence a complement of another sequence when the sequences have two identical nucleotides?

Clarification of the metes and bounds is require. Claims 2-10 are rejected for being dependent from claim 1.

CLAIM REJECTIONS UNDER 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 6 and 7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

11. This rejection is necessitated by Applicant's amendments.

12. The claimed invention, which recites a "host cell" in claim 6, and "wherein the host cell is a plant cell" in dependent claim 7, has been construed as being directed to a product of nature. Further, the instant specification discloses *Arabidopsis thaliana* (product of nature) comprises the sequence of SEQ ID NO. 9 (page 4, [16]). Therefore, the claimed invention directed to a product of nature has been considered to be non-statutory subject matter.

LACK OF WRITTEN DESCRIPTION

13. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

14. This rejection is maintained with respect to claims 1-11, as recited in the previous office action mailed January 08, 2004.

RESPONSE TO ARGUMENT

15. Applicant argues that support of variants is disclosed on pages 5 and 22, Tables 1 and 3, in the instant specification. Applicant's argument has been found to be unpersuasive because full breadth of the claims 1-11 includes sequences that have not been disclosed in the instant specification.

REJECTION RE-ITERATED

16. The specification discloses SEQ ID NO: SEQ ID NO. 9. Claims 1-11 are directed to encompass gene sequences having the sequence set forth in SEQ ID NO. 9, variants, or complements of the polynucleotide set forth in SEQ ID NO. 9. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

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17. With the exception of SEQ ID NO: 9, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. In *Fiddes v. Baird*, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that: "...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

18. Therefore, only SEQ ID NO: 9 but not the full breadth of the claims 1-11 meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

CLAIM REJECTIONS - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. Claims 1-11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Millar et al. (May 1999).

21. This rejection is maintained with respect to claims 1-11, as recited in the previous office action mailed January 08, 2004.

RESPONSE TO ARGUMENT

22. Applicant argues that claims 1 and 11 have overcome the instant prior art rejection because said claims no longer recite the limitation of “or fragment”. The claim amendments have been fully considered and found to be unpersuasive because the prior art rejection is directed to one of the two optional embodiments of the claimed invention as recited in claims 1 and 11. Specifically, the disclosure of Millar et al. is directed to the embodiment of a polynucleotide sequence having the sequence set forth in SEQ ID NO. 9 which has been cited below as being anticipated by the prior art.

REJECTION RE-ITERATED

23. Millar et al. discloses an isolated Arabiopsis polynucleotide (AF129511, positions 437-440) sequence having the sequence set forth in SEQ ID NO. 9 (Figure 3), as in instant claims 1, 2, and 11. The sequence of AF129511 is inserted into an expression vector and transformed into transgenic a plant or seed (page 835, column 1, Construction of the Transformation Vector and Generation of Transgenic Plants §), as in instant claims 2-10.

CONCLUSION

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24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

25. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

26. This application contains claims 12-17 drawn to an invention nonelected with traverse, filed October 30, 2003. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

27. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 872-9306.

28. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

29. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

30. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

32. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

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C. Dune Ly

8/25/04

Art. N. March 8/30/04
[Signature]